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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,373	03/30/2001	Sarita Chauhan	BC1032 US NA	7359

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 10/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,373

Applicant(s)

CHAUHAN ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 21, 22 and 24-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 11-13, 15-19, 23 and 46 is/are rejected.
- 7) ☒ Claim(s) 10, 14 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 9.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The provisional application upon which priority is claimed provides adequate support under 35 U.S.C. 112 for claim of this application.

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-5, 9-20, 23 and 46 in Paper No. 8 is acknowledged. Applicant's election of SEQ ID NO: 5 and ATCC PTA-1177 is also acknowledged.

Claim Objections

2. Claims 9, 11-13, 15-19 and 46 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-5 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The specification discloses several species of nitrilase enzyme sequences. However, the genus claimed includes variants for which no written description is provided in the specification. This is expressly permitted by the language of the specification which defines "substantially similar" as "modifications of the nucleic acid fragments of the instant invention such as substitution, deletion or insertion of one or more nucleotide bases that do not substantially affect the functional properties of the resulting transcript (page 23, lines 15-18 of the specification)."

Because the "functional properties" are not defined by this quote, this language permits any alteration of the sequence. Further, the percent homology language includes no functional requirement so that there is no common structure which must be preserved.

This large genus is represented in the specification by only the particularly named SEQ ID Nos. Thus, applicant has express possession of only two particular nitrilase sequences, in a genus which comprises hundreds of millions of different

Art Unit: 1637

possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific nucleic and amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the nitrilase gene by "encoding a substantial portion (see claim 1, paragraph (a))", by "substantially similar (see claim 1

paragraph (b))", or using the hybridization language of paragraph (c) of claim 1 lack any specific required structure. Thus, these claims present precisely the situation of naming a type of material which is generally known to likely exist, but, except for the two specific nitrilase sequences given fails to provide descriptive support for these generic claims.

With regard to claim 23, the situation is even worse. This product by process claim lacks even the minimal structural requirements imposed by claim 1 in which particular SEQ ID Nos must at least be the starting point for the alteration. In claim 23, there is absolutely no structure given and consequently, this claim is solely a definition by function.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

As already noted, the current claims define the nitrilase nucleic acids solely by their functional utility, as fragments or components capable of hybridization to specific sequences, without any definition of the particular genus of sequences claimed.

In Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly

Art Unit: 1637

disclosed which encode the nitrilase enzymes disclosed. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

3. Claim 2 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While the use of algorithms in a claim is not per se indefinite, the limitation to a 71% identity using the Needleman and Wunsch algorithm is indefinite where the specific parameters of the alignment are not given. For example, in that algorithm, parameters such as the gap value can vary. Thus, in the current case, where the prior art cited below has a 71.274% identity based upon a Smith-Waterman search using the parameters given on page 1, left side, and an 89% similarity, the claim is interpreted broadly to permit the prior art reference to anticipate the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al (Biochemistry (1992) 31:9000-9007).

Kobayashi et al teaches an isolated nucleic acid sequence fragment that encodes a nitrilase enzyme (see page 9004, figure 3) which sequence:

Art Unit: 1637

- i) encodes a substantial portion of the amino acid sequence of SEQ ID NO: 5,
- ii) is substantially similar to both the entirety and to a portion of SEQ ID NO: 5
- iii) would hybridize to SEQ ID NO: 5 under the stated conditions,
- iv) encompasses the completely complementary strand
- v) is 71.274 % identical to SEQ ID NO: 5 (see attached alignment).

With regard to the limitation in claim 5 that the nucleic acid be isolated from *Acidovorax* strain, in the absence of any structural limitations imposed by this claim limitation, this source designation is not given patentable weight. As MPEP 2111 notes "During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification". Here, the broadest reasonable interpretation is that the source gives no patentable weight. As MPEP 2113 notes "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Here, the only difference between the products is the claimed method of making. Since the products are the same given the scope of the claim, the products are anticipated. This same argument applies with even greater force to claim 23.

Allowable Subject Matter

6. Claims 10, 14 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1637

7. The following is a statement of reasons for the indication of allowable subject matter: These claims are drawn to specific deposited plasmids in microorganisms which deposits are not taught nor suggested by the prior art. Further, it is noted that the specification complies with the deposit rules on page 5, lines 25-34.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1637

October 1, 2002